MAY 1 6 2002

K021232

Attachment 4
510(k) Summary

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Christina L. Rowe Associate II, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Information:	E-mail: rowec@bsci.com Phone: 408.895.3526 Fax: 408.895.2202
Device Common Name	Catheter, Intracardiac, High Density Array
Device Proprietary Name	Constellation® Multiple Electrode Recording and Pacing Catheter
Device Classification	Class II, MTD
Predicate Device	Catheter, Intracardiac, High Density Array
Predicate Device Manufacturer(s)	Boston Scientific/EP Technologies Inc.
Predicate Device Proprietary Name(s)	Constellation® Multiple Electrode Recording and Pacing Catheter
Predicate Device Classification Number	MTD
Predicate Device Classification(s)	21 CFR § 870.1220

Date Summary Was Prepared:

April 17, 2002

Description of the Device:

The Boston Scientific/EP Technologies (EPT) Constellation® Multiple Electrode Recording and Pacing Catheter is a sterile, single use device used to detect and record electrical potentials from the endocardial surfaces of the heart, and to deliver externally generated pacing stimuli. The distal, expandable "basket" assembly is, in essence, eight miniature octapolar "catheters". The basket assembly contains an array of between 32 to 64 electrodes mounted along eight resilient support structures called "splines". Several configurations are available, including unipolar (electrodes evenly spaced), bipolar (electrodes evenly distributed into pairs), and lower density arrays. EPT furnishes the

Constellation® Catheter either with or without the Duraflo® coating. EPT also furnishes accessories that include EPT Constellation Accessory Cables (sterile, re-useable), an EPT Constellation Pacing Switchbox (non-sterile, re-useable), and EPT Constellation extension cables (non-sterile, re-useable).

Intended Use:

For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation® Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

Additionally, all Constellation® Catheter Directions for Use (DFU) contain a boxed warning with text which is 2 points larger than the surrounding text.

> The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and therapeutic treatment of atrial arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

Technological Characteristics:

The modified Constellation® catheter features identical technological characteristics to currently approved Constellation® models under K983171, K992777, K000277, and K003782. The only new characteristic of the proposed Constellation® model 8031M is electrode spacing reduced from a range between 2 - 13mm to a range between 1 - 13mm.

Comparison to Predicate Device:

	Constellation® Catheter 38, 48, 60 & 75 mm	Modified Device
510(k) Reference	K983171; K992777; K000277; K003782	Current Submission
Intended Use	Intracardiac electrophysiological mapping and or pacing	Same
Device Description	Multiple Electrode Mapping and Pacing Catheter	Same
Electrode Spacing	2 - 13 mm	1 - 13 mm
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/EPT	Same
Device Classification	Class II / MTD 21 CFR 870.1220	Same

Summary of the Non-clinical Data:

Performance testing with the new configuration demonstrated substantial equivalence with the predicate device. Specifically, non-clinical tests included electrical integrity testing.

Abstract of the Clinical Data:

Bench testing was sufficient to assess safety and effectiveness and, thus, to establish the substantial equivalence of the new configuration. Clinical data was therefore determined to be unnecessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2002

Ms. Christina L. Rowe
Associate II, Regulatory Affairs
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134

Re: K021232
Trade Name: Constellation® Multiple Electrode Recording and Pacing Catheters System
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: MTD
Dated: April 17, 2002
Received: April 18, 2002

Dear Ms. Rowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

WARNING: The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

The Warning must be presented in within a black box, and the font size of the text should be at least 2 points larger than any surrounding text. The Warning must be present on the first page of your Operator's Manual, and on the packaging for each individual device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

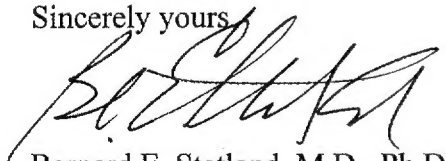
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021232

Device Name: Constellation® Multiple Electrode Recording and Pacing Catheters System

Indications For Use for device:

For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation® Multiple Electrode Recording and Pacing Catheters System may also be used for delivery of externally generated pacing stimuli.

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021232